

VIA FACSIMILE

LUD-5256.4 DIV J/NDH (09903230)

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28, 2003.

Laurie Olds
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Applicant : Hiles, et al.
Serial No. : 09/325,095
Filed : June 3, 1999
For : METHODS FOR DETERMINING EXPRESSION
OF A P13 KINASE GENE
Art Unit : 1645
Examiner : J. Hines

March 28, 2003

Hon. Commissioner of Patents
and Trademarks
Washington, D.C. 20231
Attn: SPE Lynette Smith

LETTER
RE: INTERVIEW

An interview has been scheduled for Wednesday, April 2 at 10:00 a.m. in connection with the
above referenced case. Applicants confirm the interview, and wish to submit the following for
discussion at the interview.

I. POINT 4: DRAWINGS

The examiner indicates "The drawing corrections will no longer be held in abeyance."
Applicants request an explanation of this, as there is no indication of allowable subject matter at
this time, and it is believed to be inappropriate to require the expense of formal drawings before
allowance.

II. POINT 7: THE OBJECTION TO CLAIM 58

The examiner states that claim 58 is improperly dependent because in claim 51, "the
sample is already RNA." The sample could include cDNA rather than RNA.

III. POINT 8: THE WRITTEN DESCRIPTION REJECTION

The examiner discusses claims 51 & 59.

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JM
7/18/03

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APPLICANTS HEREBY AGREE TO CANCEL CLAIM 59.

With respect to the rest of the rejection, as has been pointed out previously, the "sequences" set forth in claim 56 encompass hundreds of sequences. Hence, it is not seen how there is a lack of written description. If this is an enablement rejection, then it is pointed out that the burden is on the examiner to show lack of enablement.

Finally, a transcript of the gene, i.e., the cDNA, is disclosed. See SEQ ID NO: 32, and SEQ ID NO: 35, for example. These were found patentable in U.S. Patent No. 5,846,824. Please see claim 1. Note section (c). Copies of the front page and the issued claims are attached.

IV. POINT 9: THE NEW MATTER REJECTION

It appears that this is a rejection, expressly of claim 59. This being the case, the cancellation of the claim will render it moot. If this is not the case, applicants do not understand the rejection.

V. POINT 10: OMISSION OF ESSENTIAL STEPS

Again, applicants do not understand this rejection, but have agreed to cancel 59.

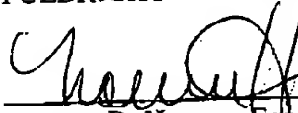
The claims do recite the use of, e.g., labels. Please see claim 52. Methods, such as PCR, do not necessarily use or need labels.

VI. POINT 11: THE REJECTION UNDER 35 USC §112, SECOND PARAGRAPH

Applicants do not understand this rejection, as the claims are written in the same way as all assay claims are.

Respectfully submitted,

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Norman D. Hanson, Esq.
Registration No. 30,946

88647



US005846824A

United States Patent [19]

Hiles et al.

[11] Patent Number:

5,846,824

[45] Date of Patent:

Dec. 8, 1998

[54] **POLYPEPTIDES HAVING KINASE
ACTIVITY, THEIR PREPARATION AND USE**[75] Inventors: Ian D. Hiles; Michael J. Fry; Ritu
Dhand; Michael D. Waterfield; Peter
J. Parker; Masayuki Otsu; George
Panayontou; Stefano Volinia; Ivan
Gout, all of London, England[73] Assignee: Ludwig Institute for Cancer
Research, New York, N.Y.

[21] Appl. No.: 780,872

[22] Filed: Jan. 9, 1997

Related U.S. Application Data

[62] Division of Ser. No. 162,081, Feb. 7, 1994.

[51] Int. Cl.⁶ C12N 5/10; C12N 5/16;
C12N 15/54; C12N 15/63[52] U.S. Cl. 435/348; 435/320.1; 435/325;
536/23.2; 536/24.3[58] Field of Search 536/23.2, 23.5;
536/24.3; 435/320.1, 325, 348, 252.3, 254.11**References Cited****PUBLICATIONS**

Otsu et al., Cell 65:91-104, 1991.

Primary Examiner—Eric Grimes
Attorney, Agent, or Firm—Fulbright & J Worski**[57] ABSTRACT**

This invention relates to new polypeptides which exhibit kinase activity or, more specifically, which show phosphoinositide (PI) 3-kinase activity. Such polypeptides are involved in pathways responsible for cellular growth and differentiation. An isolated polypeptide which possesses PI3-kinase activity when produced by recombinant production in insect cells is disclosed.

8 Claims, 76 Drawing Sheets

5,846,824

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-continued

(C) STRANDEDNESS: single
(D) TOPOLOGY: linear

(iii) SEQUENCE DESCRIPTION: SEQ ID NO: 30:

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Gly Asp Asp Leu Arg Gln Asp Leu Leu Gln Ile Ile Met Gln Leu Asp
1          5          10          15
Leu Pro Tyr Leu Thr Gly Gly Ile Gln Ile Asn Gly Ile Gly Leu Asn
20          25          30
Ile Asp Phe Val Ser Cys Ala Gly Tyr Cys Val Thr Tyr Ile Leu Gly
35          40          45
Gly Asp Arg His Asp Asn Gly Leu Phe His Ile Asp Phe Gly
50          55          60

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We claim:

1. An isolated nucleic acid molecule which encodes the catalytic (110 kD) subunit of PI-3 kinase, selected from the group consisting of:
 - (a) the nucleotide sequence set forth in SEQ ID NO: 32.
 - (b) the nucleotide sequence set forth in SEQ ID NO: 35. and
 - (c) a nucleotide sequence which hybridizes to the complement of at least one of (a) and (b).
2. The isolated nucleic acid molecule of claim 1, wherein said isolated nucleic acid molecule encodes a polypeptide consisting of the amino acid sequence encoded by the nucleotide sequence set forth in SEQ ID NO: 32 SEQ ID NO: 35.
3. The isolated nucleic acid molecule of claim 1, wherein said isolated nucleic acid molecule encodes a polypeptide consisting of the amino acid sequence set forth in SEQ ID NO: 37.
4. Expression vector comprising the isolated nucleic acid molecule of claim 2, operably linked to a promoter.
5. The expression vector of claim 4, wherein said promoter is regulatable.
6. Host cell transformed or transfected with the expression vector of claim 4.
7. The host cell of claim 6, wherein said host cell is an insect cell.
8. Isolated nucleic acid molecule consisting of any one of
 - (a) nucleotides 487-525 of SEQ ID NO: 32.
 - (b) nucleotides 876-1011 of SEQ ID NO: 32.
 - (c) nucleotides 1321-1392 of SEQ ID NO: 32.
 - (d) nucleotides 1864-1944 of SEQ ID NO: 32.
 - (e) nucleotides 1969-2016 of SEQ ID NO: 32.
 - (f) nucleotides 2035-2097 of SEQ ID NO: 32.
 - (g) nucleotides 2134-2160 of SEQ ID NO: 32.
 - (h) nucleotides 2602-2646 of SEQ ID NO: 32.
 - (i) nucleotides 2653-2724 of SEQ ID NO: 32.
 - (j) nucleotides 2773-2823 of SEQ ID NO: 32.
 - (k) nucleotides 2845-2898 of SEQ ID NO: 32.
 - (l) nucleotides 2959-3030 of SEQ ID NO: 32.
 - (m) nucleotides 3091-3189 of SEQ ID NO: 32. and
 - (n) nucleotides 3163-3189 of SEQ ID NO: 32.

